Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO

Sheet

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Cor	nplete if Known	
Application Number	10/520,104	
Filing Date	January 3, 2005	
First Named Inventor	Henry Daniell	
Art Unit	1635	-
Examiner Name	Kubelik	
Attorney Docket Number	10669-040	

Examiner	Cite	Document Number	Publication Date	Name of Patentee or	Pages, Columns, Lines, Where
Examinei Initials*	No.1	Document Number	MM-DD-YYYY	Applicant of Cited Document	Relevant Passages or Relevant
	1,0.	Number-Kind Code ² (# known)		Figures Appear	
		^{US-} 4,462,985	07-31-1994	Cummins, Jr.	
		^{US-} 5,932,479	08-03-1999	Daniell, et al.	
		^{US-} 5,693,507	12-02-1997	Daniell, et al.	
		^{US-} 5,198,345	03-30-1993	Gwynne, et al.	
		US-			
		US-			
		US-	•		
		US-			
		US-			
	<u> </u>	US-		·	·
		US-			
	1	US-			
		US-			
	1	US-			
	1	US-			

		FORE	IGN PATENT DOCL	JMENTS		
Examiner Initials*	Cite No.1	Foreign Patent Document	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages	6
1110010	110.	Country Code ³ "Number ⁴ "Kind Code ⁵ (if known)	MM-DD-YYYY		Or Relevant Figures Appear	L
		WO99/10513	03-04-1999	Daniell, H.		_
						}
						<u> </u>
	<u> </u>				<u> </u>	-
	<u> </u>					╄

Commission		Date	
Examiner	1	Considered	1
Signature		Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. Applicant's unique citation designation number (optional). See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. Senter Office that issued the document, by the two-letter code (WIPO Standard ST.3). For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Linder the Panerwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute	e for form 1449/PT	0		Complete if Known			
Guosiiui	6 107 101111 144511 1	•		Application Number	10/520,104		
INFO	ORMATIC	N DIS	CLOSURE	Filing Date	January 3, 2005		
STA	TEMENT	BY A	PPLICANT	First Named Inventor	Henry Daniell		
				Art Unit	1635		
	(Use as many sheets as necessary)			Examiner Name .	Kubelik		
Sheet	2	of	12	Attorney Docket Number	10669-040		

number(s), publisher, city and/or country where published. ABKEVICH, V. et al. "What can disulfide bonds tell us about protein energentics, function and folding: simulations and bioninformatics analysis" Journal of Molecular Biology, 2000, pp. 975-985, Vol 300. No.4. ARAKAWA, T. et al. "Expression of cholera toxin B subunit oligomers in transgenic potato plants" Transgenic Research, 1997, pp. 403-413, Vol. 6, No. 6. BARON, S. et al. "The interferons, Mechanisms of action and clinical applications" JAMA, 1991, pp. 1375-1383, Vol. 266. No. 10. BENDICH, A. J. et al. "Why do chloroplasts and mitochondria contain so many copies of their genome?" BioEssays, June 1987, pp. 279-282, Vol. 6, No. 6.	
Research, 1997, pp. 403-413, Vol. 6, No. 6. BARON, S. et al. "The interferons, Mechanisms of action and clinical applications" JAMA, 1991, pp. 1375-1383, Vol. 266. No. 10. BENDICH, A. J. et al. "Why do chloroplasts and mitochondria contain so many copies of their genome?" BioEssays, June 1987, pp. 279-282, Vol. 6, No. 6.	
1375-1383, Vol. 266. No. 10. BENDICH, A. J. et al. "Why do chloroplasts and mitochondria contain so many copies of their genome?" BioEssays, June 1987, pp. 279-282, Vol. 6, No. 6.	
BioEssays, June 1987, pp. 279-282, Vol. 6, No. 6.	
PHO IMANU. S. et al. Plant tissue Culture: Application and Limitations, 1990. Elsevier, Amsterdam, The	
Netherlands.	
BOGORAD, L. "Engineering chloroplasts: an alternatice site for foreign genes, proteins, reactions and products" Trends Biotechnol., 2000, pp. 257-263, Vol. 18, No. 6.	
BOVOLENTA, C. et al. "Molecular Interactions Between Interferon Consensus Sequence Binding Protein and Members of the Interferon Regulatory Factor Family, PNAS, 1994, pp. 5046-5050, Vol. 91, No. 11.	
BRADFORD, M. "A rapid and sensitive method for the quantitation of microgram quantities of protein utilizing the principle of protein-dye binding" Analytical Biochemistry, 1976, pp. 248-254. Vol. 72, No. 1-2.	
BRAUN, A. et al. "Protein Agreegates Seem to Play a Key Role Amoung the Parameters Influecing the Antigenicity of Interferon Alphs (IFN-) in Normal and Transgenic Mice" Pharmaceutical Research, 1997, pp. 1472-1478, Vol. 14, No. 10.	
	BOGORAD, L. "Engineering chloroplasts: an alternatice site for foreign genes, proteins, reactions and products" Trends Biotechnol.; 2000, pp. 257-263, Vol. 18, No. 6. BOVOLENTA, C. et al. "Molecular Interactions Between Interferon Consensus Sequence Binding Protein and Members of the Interferon Regulatory Factor Family, PNAS, 1994, pp. 5046-5050, Vol. 91, No. 11. BRADFORD, M. "A rapid and sensitive method for the quantitation of microgram quantities of protein utilizing the principle of protein-dye binding" Analytical Biochemistry, 1976, pp. 248-254. Vol. 72, No. 1-2. BRAUN, A. et al. "Protein Agreegates Seem to Play a Key Role Amoung the Parameters Influecing the Antigenicity of Interferon Alphs (IFN-) in Normal and Transgenic Mice" Pharmaceutical Research, 1997, pp.

Examiner	Date	1
Signature	Considered	
Signature		l

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burdén, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO:

Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

PTO/SB/08b (01-08)
Approved for use through 07/31/2008. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
a collection of information unless it contains a valid OMB control number.

Substitut	e for form 1449/PTO				Complete if Known
Substitut	16 101 101111 1443/F 10			Application Number	10/520,104
INFO	ORMATION	DIS	CLOSURE	Filing Date	January 3, 2005
STA	TEMENT E	BY A	PPLICANT	First Named Inventor	Henry Daniell
	///	4		Art Unit	1635
	(Use as many she	ets as n	ecessary)	Examiner Name	Kubelik
Sheet	3	of	12	Attorney Docket Number	10669-040

	L 0''	NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	R10	BRIXEY, M. et al. "The Chloroplast psbA promoter is more efficient in Escherichia coli than the T7 promoter for hyperexpression of a foreign protein" Biotechnology Letters, 1997, pp. 395-400. Vol. 19, No. 4.	
·	R11	BRUICK, R. et al. "Light-activated translation of chloroplast mRNAs" Trends in Plant Science, 1999, pp. 190-195, Vol. 4, No. 5.	
	R12	CARLSON, P. S. et al. "The use of protoplasts for genetic research" PNAS, 1973, 598-602, Vol. 70, No. 2.	
	R13	CASTELRUIZ, Y. et al. Hepatology, 1999, pp. 1900-1904.	
	R14	COLAMONICI, O. et al. "Characterization of three monoclonal antibodies that recognize the interferon 2 receptor" PNAS, 1990, pp. 7230-7234, Vol. 87, No. 18.	
	R15	COOK, J. et al. "Differential responsiveness of a splice variant of the human type I interferon receptor to interferons" J. Biol. Chem., 1996, pp. 13448-13453, Vol. 271, No. 23.	
-	R16	COWLEY, D. et al. "Expression, purification and characterization of recombinant human proinsulin" FEBS Letters, 1997, pp. 124-130, Vol. 402, No. 2-3.	
	R17	CRAMER, C. et al. "Transgenic plants for therapeutic proteins: linking upstream and downstream strategies" Current Topics Microbiol. Immunol., 1999, pp. 95-118, Vol. 240.	
	R18	CROSS, J. et al. "Constitutive and trophoblast-specific expression of a class of bovine interferon genes" PNAS, 1991, pp. 3817-3821, Vol. 88, No. 9.	

Examiner	Date		
Signature	Considered	·	

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO:

Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

PTO/SB/08b (01-08)

Approved for use through 07/31/2008, OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

	te for form 1449/F	•		Teganes to respons to a sensore	Complete if Known
Substitui	te for form 1449/r	-10		Application Number	10/520,104
INFO	ORMATI	ON DIS	CLOSURE	Filing Date	January 3, 2005
STA	TEMEN	T BY A	PPLICANT	First Named Inventor	Henry Daniell
				Art Unit	1635
	· (Use as man	ıy sneets as n	ecessary)	Examiner Name	Kubelik
Sheet	4	of	12	Attorney Docket Number	10669-040

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	R19	CROSSIŃ, K. et al. "Evidence that microtubule depolymerization early in the cell cycle is sufficient to initiate DNA synthesis" Cell, 1981, pp. 61-71, Vo;l. 23, No. 1.	
·····	R20	Daniell, H. et al. "Chloroplast culture. IX. Chlorophyll(ide) a biosynthesis in vitro rates higher than in vivo" Biochem. Biophys. Res. Commun., May 31, 1982, pp. 466-470. Vol. 106, No.2.	
	R21	Daniell, H. et al. "Uptake and expression of bacterial and cyanobacterial genes by isolated cucumber etioplasts" Proc. Natl. Acad. Sci. USA, September 1987, pp. 6349-6353, Vol. 84.	
	R22	Daniell, H. et al. "Transient foreign gene expression in chloroplasts of cultured tobacco cells after biolistic delivery of chloroplast vectors" Proc. Natl. Acd. Sci. USA, January 1990, pp.88-92, Vol. 87, No.1.	
	R23	Daniell, H. et al. "Transient expression of B-glucuronidase in different cellular compartments following biolistic delivery of foreign DNA into wheat leaves and calli" Plant Cell Reports, 1991, pp. 615-619, Vol. 9, No. 11.	
	R24	Daniell, H. et al. "Foreign gene expression in chloroplasts of higher plants mediated by tungsten particle bombardment" Methods Enzymol., 1993, pp. 536-556, Vol. 217.	
 	R25	Daniell, H. et al. "Transformation and foreign gene expression inplants by microprojectile bombardment" Methods Mol. Biol., 1997, pp. 463-489, Vol. 62.	
	R26	Daniell, H. et al. "Containment of herbicide resistance through genetic engineering of the chloroplast genome" Nature Biotechnoloby, April 1998, pp. 345-348, Vol. 16, No. 4.	
	R27	ZHOU, M. et al. "Universal TA cloning" Curr. Issues Mol. Biol., 2000, pp. 1-7, Vol. 2, No. 1.	

Examiner	Date		
Signature	Considered		
0.5		 	

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Approved for use through 07/31/2008. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
b a collection of information unless it contains a valid OMB contains as a collection of information unless it contains a valid OMB contains as a collection of information unless it contains a valid OMB contains as a collection of information unless it contains a valid OMB contains as a collection of information unless it contains a valid OMB contains as a collection of information unless it contains a valid OMB contains as a collection of information unless it contains a valid OMB contains a valid OMB contains as a collection of information unless it contains a valid OMB contains as a collection of information unless it contains a valid OMB contains as a collection of information unless it contains a valid OMB contains as a collection of information unless it contains a valid OMB contains as a collection of information unless it contains a valid OMB contains a valid OMB contains as a collection of information unless it contains a valid OMB contains a v

	e for form 1449/PTO		t of 1995, no persons ar	Complete if Known			
Subsului	e for form 1449/P10		•	Application Number	10/520,104		
INFO	DRMATION	I DIS	CLOSURE	Filing Date	January 3, 2005		
STA	TEMENT E	3Y A	PPLICANT	First Named Inventor	Henry Daniell		
				Art Unit	1635		
	(Use as many sh	eeis as n	ecessa <i>ry,</i>	Examiner Name	Kubelik		
Sheet	5	of	12	Attorney Docket Number	10669-040		

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	R28	DANIELL, H. et al. "Medical molecular farming: production of antibodies, biopharmaceuticals and edible vaccines in plants" Trends in Plant Science, may 2001, pp. 219-226, Vol. 6, No. 5.	
	R _. 29	DANIELL, H. et al. "Expression of the Native Cholera Toxin B Subunit Gene and Assembly as Functional Oligomers in Transgenic Tobacco Chloroplasts" Journal of Mol. Biol., 2001 pp. 1001-1009, Vol. 311.	
	R30	DANIELLI, H. et al. "Marker free transgenic plants: engineering the chloroplast genome without the use of antibiotic selection" Curr. Genet., 2001, pp. 109-116, Vol. 39.	
	R31	DANIELL, H. et al. "Milestones in chloroplast genetic engineering: an environmentally friendly era in biotechnology" Trends in Plant Science, February 2002, pp. 84-91, Vol. 7, No. 2.	
	R32	DANIELL, H. et al. "Molecular strategies for gene containment in transgenic crops" Nature Biotechnology, 2002, pp. 581-586, Vol. 20.	
	R33	DANON, A. "Translational regulation in the chloroplast" Plant Physiol., 1997, pp. 1293-1298, Vol. 115, No. 4.	
	R34	DE COSA, B. et al. "Overexpression of the Bt cry2 Aa2 operon in chloroplasts leads to formation of insecticidal crystals" Nature Biotechnology, January 2001, pp. 71-74, Vol. 19.	
	R35	DE GRAY, G. et al. "Expression of an Antimicrobial Peptide via the Chloroplast Genome to Control Phytopathogenic Bacteria and Fungi" Plant Physiology, November 2001, pp. 852-862, Vol. 127.	
	R36	DER, S. et al. "Involvement of the double-stranded-RNA-dependent kinase PKR in interferon expression and interferon-mediated antiviral activity" PNAS, 1995, pp. 8841-8845, Vol. 92, No. 19.	

Examiner	Date	
	Considered	
Signature		

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

1 Applicant's unique citation designation is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including the process application of the complete application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450.

1 Applicant is to place the process of the process of the process of the complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450.

1 Applicant is to place the process of the p Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Approved for use through 07/31/2008. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO					Complete if Known
Substituti	8 101 101111 1449/1-10			Application Number	10/520,104
INFO	INFORMATION DISCLOSURE STATEMENT BY APPLICANT	CLOSURE	Filing Date	January 3, 2005	
STA	TEMENT E	Y A	PPLICANT	First Named Inventor	Henry Daniell
(Use as many sheets as necessary)				Art Unit	1635
				Examiner Name	Kubelik
Sheet	6	of	12	Attorney Docket Number	10669-040

Examiner	Cite	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of	_
initials*	No. ¹	the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	R37	DIMMOCK, N. et al. "The immune system and interferon" Introduction to Modern Virology, Fourth Edition, 1994, pp. 205-213.	
	R38	EDWARDS, K. et al. "A simple and rapid method for the preparation of plant genmic DNA for PCR analysis" Nucleic Acids Research, January 2, 1991, pp. 1349, Vol. 19, No. 6.	
	R39	EIBL, C. et al. "In vivo analysis of plastid psbA, rbcL and rp/32 UTR elements by chloroplast transformation: tobacco plastid gene expression is controlled by modulation of transcript levels and translation efficiency", Plant, 1999, pp. 333-345, Vol. 19.	
	R40	EDERBAUM, O. et al. " Expression of active human interferon beta in transgenic plants" J Interferon Res, 1992, pp. 449-453, Vol. 12.	
	R41	FERBAS, J. et al. "CD4+ blood cells are potent producers of IFN-alpha in response to in vitro HIV-1 infection" J Immunol, 1994, pp. 4649-4662, Vol. 152, No. 9.	
	R42	FERNANDEZ-SAN MILLAN, A. et al. "A chloroplast transgenic approach to hyper-express and purify human serum albumin, a protein highly susceptible to proteolytic degradation" Plant Biotechnol J, 2003.	
	R43	GERACE, L. "Cell biology: Traffic control and stuctural proteins in the eukaryotic nucleus" Nature, 1985, pp. 508-509, Vol. 318, No. 6046.	
	R44	GLICK, B. et al. Molecular Biotechnology: Principles and Applications of Recombinant DNA, 2d edition, 1998, ASM press, Washington, D.C.	
	R45	GOMEX-ORELLANA, et al. "Advances in the oral delivery of proteins" Exp. Opin. Ther. Patents, 1998, pp. 223-234, Vol. 8, no. 3.	

Examiner	Date	
Chairme	Campidaged	
Signature	Considered	

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including to the theorems, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO:

Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Approved for use through 07/31/2008. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Substitut	e for form 1449/PTO			Complete if Known					
Cubsing			Application Number	10/520,104					
INFO	ORMATION	DIS	CLOSURE	Filing Date	January 3, 2005				
STA	TEMENT B	BY A	PPLICANT	First Named Inventor	Henry Daniell				
	(Use as many she			Art Unit	1635				
	(Use as many sne	612 92 H	ecessary)	Examiner Name	Kubelik				
Sheet	7	of	12	Attorney Docket Number	10669-040				

Examiner Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue	T ²
		number(s), publisher, city and/or country where published.	
	R46	GUDA, C., et al. "Stable expression of a biodegradable protein-based polymer in tobacco chloroplasts", Plant Cell Report, 2000, pp. 257-262, Vol. 19.	
	R47	GUTTERMAN, J. et al. "Cytokine therapeutics: lessons from interferon" PNAS, 1994, pp. 1198-1205, Vol. 91, No. 4.	
	R48	RUF, S. et al. "Stable genetic transformation of tomato plastids: high level foreign protein expression in fruits" Nature Biotechnology 2001, pp. 870-875, Vol. 19.	
	R49	HAQ, T. A. et al. "Oral immunization with a recombinant bacterial antigen produced in transgenic plants" Science, May 5, 1995, pp. 714-716, Vol. 268, No. 5211.	
	R50	HAJDUKIEWICZ, P. et al. "The two RNA polymerases encoded by the nuclear and the plastid compartments transcribe distinct groups of genes in tobacco plastids" EMBO J., 1997, pp. 4041-4048, ol. 16, No. 13.	
	R51	HEATH, D. G. et al. "Protection against experimental bubonic and pneumonic plague by a recombinant capsular F1-V antigen fusion protein vaccine" Vaccine, July 1998, pp. 1131-1137, Vol. 16, No. 11-12.	
	R52	HEIFETZ, P. et al. "Protein expression in plastids" Current Opinion in Plant Biology, 2001, pp. 157-161, Vol. 4, No. 2.	
	R53	HENCO, K. et al. "Structural relationship of human interferon alpha genes and pseudogenes." Journal of Molecular Biology, 1985 pp. 227-260, Vol.185, No. 2.	
	R54	ISAACS, A. et al. "Virus interference. I. the interferon" Proceddings of the Royal Society of London. Series B, Biological Sciences, September 1957, pp. 258-267, Vol. 147, No. 927.	

Examiner	Date	•
Signature	Considered	

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the Individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO:

Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

	le for form 1449/PTO	N DISCLOSURE BY APPLICANT Sheets as necessary) Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number. Complete if Known 10/520,104 Filing Date January 3, 2005 Henry Daniell Art Unit 1635 Examiner Name Kubelik			
Causalole for form 1440/110		Application Number	10/520,104		
INFO	ORMATION	DIS	CLOSURE	Filing Date	January 3, 2005
STA	TEMENT E	BY A	PPLICANT	First Named Inventor	Henry Daniell
	// los se menu abo	ota os s	occesand	Art Unit	1635
ļ	(Ose as many sne	ets as III		Examiner Name	Kubelik
Sheet	8	of	12	Attorney Docket Number	10669-040

Examiner	Cite	NON PATENT LITERATURE DOCUMENTS Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of	
Initials*	No. ¹	the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	R55	KAVANAGH, T. et al. "Homelogous plastid DNA transformation in tobacco is mediated by multiple recombination events" Genetics, 1999, pp. 1111-1122, Vol. 152, No. 3.	
	R56	KIM, J. et al. "Protein disulfide isomerase as a regulator of chloroplast translational activation" Science, December 1997, pp. 1954-1957, Vol. 278.	
	R57	KONG, Q. et al. "Oral immunization with hepatitis B surface antigen expresseed in transgenic plants" PNAS, 2001 pp. 11539-11544, Vol. 98, No. 20.	
	R58	KUSNADI, A. et al. "Pruduction of recombinant proteins in transgenic plants: practical considerations" Biotechnoloby and Bioengineering, 1997, pp. 473-484, Vol. 56, No. 5.	
<u>.</u>	R59	LAEMMLI, U. "cleavage of structural proteins during the assembly of the head of bacteriophage T4" Nature, 1970, pp. 680-695, Vol. 227.	
	R60	LAMPSON, G. et al. "Inducers of interferon and host resistance, I. double-stranded RNa from extracts of penicillium funiculosum" PNAS, 1967, pp. 782-789, Vol. 58, No. 2.	
	R61	LARREA, E. et al. "Journal of Viral Hepatitus, 2001, pp. 1-7, Vol. 8. (cited incorrectly)	
	R62	LENCER, W. I. et al. "Transcytosis of cholera toxin subunits across model human intestinal epithelia" PNAS, October 1995, pp. 10094-10098, Vol. 92.	
	R63	MALIGA, P. "Towards plastid transformation in flowering plants" TIBTECH, 1993, pp. 101-106, Vol. 11, No.3.	
			

Examiner	·	Date	
Signature		Considered	•

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the Individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO:

Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

	bstitute for form 1449/PTO IFORMATION DISCLOSURE			Complete if Known			
Substituti	6 101 101111 144 <i>31</i> 7 10			Application Number	10/520,104		
INFO	RMATION	DIS	CLOSURE	Filing Date	January 3, 2005		
STA	TEMENT B	Y A	PPLICANT	First Named Inventor	Henry Daniell		
	(Use as many she	ata ac n	onorgand	Art Unit	1635		
	(Use as many sne	ets as n	ecessary)	Examiner Name	Kubelik		
Sheet	9	of	12	Attorney Docket Number	10669-040		

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
	R64	MARTIN, W. et al. "Gene transfer from organelles to the nucleus: how much, what happens, and why?" Plant Physiol., 1998, pp. 9-17, Vol. 118, No. 1.	
	R65	MATHIOWITZ, E. et al. "Biologically erodable microspheres as potential oral drug delivery systems" Nature, March 27, 1997, pp. 410-414, Vol. 386, No. 6623.	·
	R66	MAY, G. D. et al. "Aplication of transgenic plants as production systems for pharmaceuticals" Agricultural materials as renewable resources: nonfood and industrual applications pp. 194-204, Ch. 13, American Chemical Society, Washington, D.C.	
	R67	MCBRIDE, K. E. et al. "Amplification of a chimeris Bacillus gene in chloroplasts leads to extraordinary level of an insecticidal protein in tobacco" Biotechnology, April 1995, pp. 362-365, Vol. 13, No. 4.	
	R68	MORIYA, O. et al. "Induction of hepatitis C virus-specific cytotoxic T lymphocytes in mice by immunization with dendritic cells treated with an anthrax toxin fusion protein" Vaccine, 2002, pp. 789-796, Vol. 20.	
	R69	Muller, U. et al. "Functional role of type I and type II interferons in antiviral defense" Science, 1994, pp. 1918-1921, Vol. 264, No. 5167.	
	R70	NYGREN, P. et al. "Engineering proteins to facilitate bioprocessing" TIBTECH, 1994, pp. 184-186, Vol. 12, No. 5.	
	R71	OHYA, K. et al. "Expressions of two subtypes of human IFN-a in transgenic potato plants" Journal of Interferon & Cytokine Research, Aug. 2001 pp. 585-602, Vol. 21, No. 8.	
	R72	PETRIDES, D. et al. "Computer-Aided process anlysis and economic evaluation of for biosynthetic human insulin production" Biotechnology and Bioengineering, 1995, pp. 529-554, Vol. 48, No. 1.	

Examiner	Date	
	Considered	
Signature	Considered	

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO:

Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

PTO/SB/08b (01-08) Approved for use through 07/31/2008. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

	ler the Paperwork Re	duction Ac	t of 1995, no persons ar	e required to respond to a collection	of information unless it contains a valid OMB control number. Complete if Known
Substitut	810110111111449/210			Application Number	10/520,104
INFO	DRMATION	N DIS	CLOSURE	Filing Date	January 3, 2005
STA	STATEMENT BY APPLICANT			First Named Inventor	Henry Daniell
	(Use as many sh	anto no ne	ooccand)	Art Unit	1635
	(Use as many sn	ieets as III	cessary)	Examiner Name	Kubelik
Sheet	10	of		Attorney Docket Number	10669-040

Examiner	Cite	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of	
Initials*	No.¹	the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	R73	RATHINASABAPATHY, B. "Metabolic engineering of glycine betaine synthesis: plant betaine aldehyde dehydrogenases lacking typical transit peptides are targeted to tobacco chloroplasts where they confer betaine aldehyde resistance" Planta, 1994, pp. 155-162, Vol. 193, No. 2.	
	R74	REICHERT, J. "New biopharmaceuticals in the USA: trends in development and marketing approvals 1995-1999" TIBTECH, 2000, pp. 364-369, Vol. 18, No.9.	
	R75	RUELLAND, E. et al. "Regulation of chloroplast enzyme activities by thioredoxins: activation or relief from inhibition?" Trends in Plant Science, 1999, pp. 136-141, Vol. 4, No. 4.	
	R76	RUBINSTEIN, M. et al. "The interferon receptors" CRC Crit Rev Biochem., 1986, pp. 249-277, Vol. 21.	
	R77	SANFORD, J. C. et al. "Optimizing the biolistic process for different biological applications" Methods in Enzymology, 1993, pp. 483-509, Vol. 217.	
***************************************	R78	SIDOROV, V.A. et al. "Stable chloroplast transformation in potato: use of green flourescent protein as a plastid marker" The Plant Journal, 1999, pp. 209-216, Vol. 19. No. 2.	
- · · · · · · · · · · · · · · · · · · ·	R79	SLOCOMBE, P. et al. "High-level expression of an interferon 2 gene cloned in phage M13mp7 and subsequent purification with a monoclonal antibody" PNAS, 1982, pp. 5455-5459, Vol. 79, No. 18.	
	R80	STAUB, J. M. "Accumulation of D1 polypeptide in tobacco plastid is regulated via the untranslated region of the psbA mRNA", EMBO J., 1993,pp. 601-606, Vol. 12, No. 2.	
•	R81	STAUB. J. M. et al. "High-Yield production of a human therapeutic protein in tobacco chloroplasts" Nature Biotechnology, March 2000, pp. 333-338, Vol. 18, No. 3.	
	-		

Examiner	Date
Signature	Considered

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO:

Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

PTO/SB/08b (01-08)

Approved for use through 07/31/2008. OMB 0651-0031 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO

Application Number 10/520,104

INFORMATION DISCLOSURE Filling Date January 3, 2005

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

12

Sheet

11

Application Number	10/520,104	
Filing Date	January 3, 2005	
First Named Inventor	Henry Daniell	
Art Unit	1635	
Examiner Name	Kubelik	
Attorney Docket Number	10669-040	

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
	R82	SVAB, Z et al. "high-frequency plastid transformation in tobacco by selection for a chimeric aadA gene" Proc. Natl. Acad. Sci. USA, February 1993, pp. 913-917, Vol. 90.	
	R83	SWAMINATHAN, S. et al. "Affinity purification of recombinant interferon-a on a mimetic ligand adsorbent" Protein Expression and Purification, March 1999, pp. 155-245, Vol. 15, No. 2.	
	R84	THATCHER, D. R. et al. "Related purification of recombinant human IFN-a2" Methods Enaymol, 1986, pp. 166-177, Vol. 119.	
	R85	TOMPKINS, W. "Immunomodulation and therapeutic effects of the oral use of interferon-alpha: mechanism of action" Journal of Interferon & Cytokine Research, Aug. 1999, pp. 817-828, Vol. 19, No. 8.	
	R86	TRINCHIERI, G. et al. "Antagonistic effects of interferons on the cytotoxicity mediated by natural killer cell" Federation Proceedings, 1981, pp. 2705-2710, Vol. 40.	
	R87	WALMSLEY, A. M. et al. "Plants for delivery of edible vaccines" Curr. Opin. Biotechnol. April 2000, pp. 126-129, Vol. 11, No. 2.	
v) i	R88	WILSON, V. et al. "A comparison of vertebrate interferon gene families detected by hybridization with human intereron DNA" Journal of Molecular Biology, 1983, pp. 457-475, Vol. 166.	
	R.89	YE, G. N. et al. "Optimization of delivery of foreign DNA into higher-plant chloroplasts" Plant Mol. Biol., pp. 809-819, Vol. 15, No. 6.	
	R90	Yu, J. et al. "A plant-based multicomponent vaccine protects mice from enteric diseases" Nature Biotechnology, June 2001, pp. 548-552, Vol. 19.	
	-		

Examiner		Date	•
Signature	·	Considered	
Signature			

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO:

Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

PTO/SB/08b (01-08)

Approved for use through 07/31/2008. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Substitut	te for form 1449/PTO			Complete if Known		
Judgina	10 10 10 11 1445/1 10			Application Number	10/520,104	
INFO	ORMATION	DIS	CLOSURE	Filing Date	January 3, 2005	
STA	STATEMENT BY APPLICANT			First Named Inventor	Henry Daniell · ·	
				Art Unit	1635	
	(Use as many she	ers as n	lecessary)	Examiner Name	Kubelik	
Sheet	12	of	12	Attorney Docket Number	10669-040	

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	R91	ZERGES, W. "Translation in chloroplasts" Biochimie, 2000, pp. 583-301, Vol. 82.	
	-		
		·	
	_		

Examiner	Date	
Signature	Considered	

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation Is attached.

This collection of Information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO:

Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.